K020679

MAY 06 2002

Appendix 10. Summary

PREMARKET NOTIFICATION
510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter's name, address, contact:

HemoSense, Inc.
600 Valley Way
Milpitas, CA 95035
(408) 719-1393 (phone)
(408) 719-1184 (fax)

Contact person: Judith Blunt
Date Prepared: February 28, 2002

2. Device name:

Common or usual name: Prothrombin Time Test

Classification Name: Prothrombin Time Test

Trade or Proprietary Name: INRatio

3. Predicate device

The Roche CoaguChek S™ system: device for testing Prothrombin Time and INR in whole blood.

4. Device description:

The INRatio Prothrombin Time Monitoring System uses a modified version of the one-stage prothrombin time test. After a drop of blood is applied to the test strip, it is drawn into the test area and mixed with reagents that cause coagulation to begin. The test area on the test strip is separated into three channels, each of which contains electrodes for detection of the blood clot. One channel contains the reagents to perform the prothrombin time test on the blood sample. The other two channels contain the reagents to run control tests. No external quality control tests are required for the INRatio System. The meter monitors the reactions, and calculates the PT and INR for the blood sample, which are reported on the display. If the control results are not within a set

range, it indicates a problem with the test and an error message is reported on the display instead of a result.

5. Intended use:

The INRatio is an in vitro diagnostic system that provides a quantitative prothrombin time result, expressed in seconds and as an International normalized ratio (INR). It is intended for use by healthcare professionals in monitoring patients who are on warfarin-like (coumarin) anticoagulation therapy. This device is not intended to be used for screening purposes.

6. Comparison to predicate device:

The INRatio is substantially equivalent in materials, design and intended use to other products that measure Prothrombin Time in human blood. Most notably, it is substantially equivalent to the CoaguChek S™, manufactured by Roche Diagnostics. Both products are prothrombin time devices, have the same intended use and serve the same professional, point-of-care market. The HemoSense INRatio and the CoaguChek both measure the reaction of the extrinsic coagulation pathway. Both products measure the elapsed time between the start of the reaction and the formation of fibrin from fibrinogen; the CoaguChek measure fibrin formation via the motion of magnetic particles, while the INRatio measures it via a change in the impedance of the sample.

7. Summary of Performance data:

The accuracy of the INRatio was compared to the CoaguChek S and a reference method in field studies and found to be equivalent ($r>0.90$). Precision and linearity evaluations were performed on the INRatio and the results were found acceptable. Additional testing on interfering substances, and hematocrit were performed and the results are reflected in the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Judith Blunt
Director of Clinical Affairs
& Customer Support
HemoSense, Inc.
600 Valley Way
Milpitas, California 95035

MAY 06 2002

Re: k020679
Trade/Device Name: INRatio™
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS
Dated: February 28, 2002
Received: March 4, 2002

Dear Ms. Blunt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 11. Indications for Use Statement

Feb 28, 2002

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(As required by 21 CFR 807.87(j))

510(K) Number:

Device Name: HemoSense INRatio PT Monitoring System

The HemoSense INRatio is an in vitro diagnostic system that provides a quantitative prothrombin time results, expressed in seconds and as an International Normalized Ratio (INR). It uses fresh capillary whole blood and is intended for use by health care professionals in monitoring patients who are on warfarin-type (coumarin) anticoagulation therapy. This device is not intended to be used for screening purposes.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Signed: Judith Blunt

Name: Judith Blunt

Position: Director of Clinical Affairs and Product Support

Date: Feb 28, 2002

Josephine Bartosiewicz

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(K) Number K020679